Interim Inspection Report

Sunderland Fertility Centre
0096

Date of Inspection: 18 January 2007
Date of Licence Committee: 16 April 2007

CENTRE DETAILS

Centre Address	Sunderland Royal Hospital Kayll Road Sunderland Tyne & Wear SR4 7TP
Telephone Number	0191 569 9779
Type of Inspection	Interim Treatment and Storage
Person Responsible	Menem Yossry
Nominal Licensee	Ken Bremner
Licence Number	L0096-17-a
Inspector(s)	Parvez Qureshi (Lead)
	Janet Kirkland
	Elliott Lawrence
Fee Paid - date	Not due
Licence expiry date	31 May 2009

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About the Inspection:
This inspection visit was carried out on 18 January 2007 and lasted for 5 hours. The report covers the pre-inspection analysis, the visit and information received between January 2006 and December 2006

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Sunderland Fertility Centre has been licensed since 1992 and has a good history of compliance with no previous conditions on its licence. This is a relatively small centre which mainly treats patients from Sunderland and the surrounding areas.

The centre was issued with a treatment and storage licence in June 2006. However, only five donor insemination (DI) cycles have been carried out since then. Since the last inspection no major changes have been made to the premises. The current Person Responsible (PR) has been in his role since November 2006.

The centre is open for business seven days a week between 8am and 7pm. An organisational chart is in place defining key functions and lines of accountability within the unit.

The (PR) has appropriate qualifications and experience as outlined in section 17 of the HF&E Act.

Activities of the Centre

Donor Insemination	5
Unlicensed treatments	Intrauterine Insemination Ovulation Induction Tubal Surgery
Storage	Yes

Summary for Licence Committee

Since the last inspection, some improvements have been made at the centre. However, further improvements are required to the service provided. A breach of witnessing Directions D.2004/4 was identified during the inspection.

The inspection team recommends the continuation of the centre's licence for treatment with storage subject to meeting the requirements of the witnessing Directions D.2004/4.

Risk Assessment

The current risk matrix score for centre is 11%

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation	X		
2. Quality of the service		X	
3. Premises and Equipment		X	
4. Information		X	
5. Laboratory and clinical processes		X	

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
Breach of witnessing Directions D.2004/4	Implementation witnessing directions D.2004/4.	Immediately.

Non-Compliance

Area for improvement	Action required	Time scale
Booking of counselling sessions.	Patients should be able to contact the counsellor directly.	Immediately.
Patient information.	Reviewing of information leaflets.	Within a month from report being presented to the Licence Committee.

Recommendations	Time scale
Double witnessing for all laboratory procedures.	Immediately.
Emergency trolley to be checked on a daily basis and entries made in the appropriate logs.	Immediately.

Proposed licence variations

None.

Changes/ improvements since last inspection

Appointment of a new person responsible.
The welfare of child protocol has been updated.
Recruitment of additional staff.

Additional licence conditions and actions taken by centre since last inspection

C	None.
A	None.

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance

Documentation submitted for the inspection included an organisational chart showing main functions and lines of accountability within the unit. Majority of staff have an extensive experience of working in the fertility field and have been at the centre for a considerable time.

Issues highlighted during the last inspection have been addressed by the PR. The PR confirmed that he was aware of the new HFEA Standards and the requirements of the EU Tissue and Cells Directive and currently was in the process of completing the PR assessment.

Regular multi-disciplinary team meetings are held at the centre to discuss practice related issues. The minutes of the meetings are made available to all staff and examples of these were seen during the inspection.

Within the last year no risk assessments have been carried out. However, risk management protocols are in place.

Since the last inspection, no incidents have been reported to the HFEA. However, staff interviewed during the inspection were aware of the incident reporting procedure. Recently one complaint was made at the centre and the PR stated that it was in the process of being resolved. All relevant staff are made aware of the HFEA alerts through unit meetings.

The centre has access to an ethics committee but since the last inspection no case has been referred to it. The PR confirmed that in the case of an emergency, contingency arrangements are in place with a number of local centres.

The PR stated that the centre uses the Trust's clinical governance policies.

There are no issues with the centre over the payment of treatment fees to the HFEA.

Areas for improvement
None.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

Evaluation
No improvements required.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates

Following is a summary of the donor insemination (DI) information from the HFEA Success Rate Assessment (31st March 2002 – 1st April 2005):

No data available for the age group 40-42.
The success rate for the age group 35-39 is higher than the national average.
For the age band below 35 the success rate is lower than the national average.

Areas of firm compliance

Interviews held with staff and a review of the documentation submitted for the inspection showed that 'Welfare of Child' assessment procedures are in place.

Patients' medical records are stored in secure areas with only members of the staff having access to them. Consultations with the patients are held in private rooms and any treatment offered is documented in their notes.

A total of eight patient questionnaires, relating to IUI, were returned to the HFEA. Overall the responses were positive and these were discussed with the centre staff.

The PR stated that since the last inspection only one complaint had been received and it is in the process of being resolved.

The centre has a procedure in place for making patients aware of the counselling service at their initial consultation. There is no separate charge made for counselling. Patients can attend as many sessions as they require and currently there is no waiting list.

The counsellor is member of British Infertility Counselling Association (BICA). Her CPD, which is both self and centre funded, is up to date and evidence of this was provided during the inspection. She receives regular supervision from a mentor and attends the centre's

multi-disciplinary meetings. Counselling sessions take place in a dedicated room located within the centre and the counsellor stated that she keeps the notes at home in a secure place.

The counsellor has developed a patient feed back questionnaire to evaluate the counselling service. An example of the feed back was seen during the inspection and was considered to be informative.

The counselling audit supplied to the inspection team confirmed that there were a total of 124 referrals from November 2005 to November 2006. Referral data showed that therapeutic counselling was the most frequently used.

Since the last inspection, the centre has been in the process of setting up a donor bank programme. However, the PR stated that the progress has been limited as only one donor had been recruited.

Areas for improvement

Currently the counselling sessions are booked by the centre's staff and patients are not able to contact the counsellor directly.

Other than the counselling service, there is no patient feedback procedure in place at the centre. Therefore the PR needs to develop a method to seek patients' views as a continuous improvement measure.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

Egg sharing and surrogacy.
Protection of children arrangements (for patients under 18yrs).

Evaluation

Some improvements required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
Since the last inspection no major changes have been made to the premises. All areas seen during the inspection were found to be clean and well presented. Access to the centre is restricted to staff only. The current cryostore facilities at the centre are adequate for the volume of work being carried out. The access to the cryostorage area is restricted to authorised staff only. Since the last inspection, a new dry shipper and a cryofreezer have been purchased. Up to date maintenance contracts for key pieces of equipment in the laboratory were evidenced during the inspection. The following dewars are housed in the cryostore: 1 – Quarantine 1 – Donor sperm 2 – For patient sperm samples split between the two dewars, including oncology samples. The tanks are topped up with liquid nitrogen on a weekly basis; evidenced from the fill log book. The four dewars are alarmed and connected to an autodialler. A low oxygen alarm is present in the laboratory and connected to autodialler. Oxygen alarm is tested weekly, evidenced via log. The autodialler calls the hospital switchboard and in turn the biomedical scientist from the laboratory. The centre participates in the National External Quality Assessment Service (NEQAS) scheme. Training and CPD occur inline with the trust policy. Training needs are assessed annually at appraisals. The training record for one of the IUI prepping team was evidenced. It included certificates for mandatory training: BLS and manual handling in 2006. In the event of a power failure, there is access to a back up generator located within the hospital.
Areas for improvement
On the day of the inspection no log for the checks made for the emergency trolley was available. The emergency trolley should be checked on a daily basis and entries made in the appropriate log.

Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvements required.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Five patient records for IUI were reviewed during the inspection. The notes were found to be well organised. However, some errors were identified and these were discussed with the centre's staff.
Areas of firm compliance
The centre's information management system seen during the inspection was considered to be satisfactory. Patient information submitted for the inspection was reviewed by the inspection team and was considered to be satisfactory. The following information was seen during the course of the inspection: Centre's treatment licence. Complaint procedure. HFEA printed leaflets. Counselling services. Centre's information on various treatments. No issues were raised by the HFEA Registry regarding return of treatment forms by the centre.
Areas for improvement
Some patient information leaflets require reviewing.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	1
NMC registered nurses	2
Biomedical scientist	2
Support staff (receptionists, record managers, quality and risk managers etc)	4

Summary of laboratory audit
A laboratory audit of stored samples was submitted for the inspection without any discrepancies.
Summary of spot check of stored material
A spot check of stored material was not carried out during the inspection.
Areas of firm compliance
The centre has policies in place for assessment of patients seeking treatments and for screening of patients. This was evident from the documentation submitted for inspection and discussion held with staff. The laboratory procedures for the DI and IUI treatments are divided between the Haematology and Histology/Cytology departments. Five members of the Histology/Cytology department are trained to prepare the semen samples. Two members of the Haematology department are responsible for sperm freezing and the sperm preparation laboratory, which contains the cryostorage dewars. The staff who prepare the sperm samples work on a rotational basis. The rota was evidenced during the inspections and includes weekend cover. A member of the Histology/Cytology department stated they have been trained in-house and via an external course to prepare the sperm samples. However, documented evidence was not available.

All unit staff attend mandatory training such as fire safety and Basic Life Support (BLS). Certificates of attendance were evidenced for a member of the Histology/Cytology department.

Information regarding IUI letters and diagnostic swim ups are kept in a locked draw in the Histology/Cytology department office. Evidenced during inspection.

The on call Histology/Cytology scientist is informed of potential DI/IUIs at the beginning of the week and the day before the procedure. Frozen samples are signed for the day before the procedure and transferred to a separate liquid nitrogen tank. This is recorded on an internal transfer form and signed by two members of staff. Transfer forms for four separate procedures were examined during the inspection. One form did not have a witness signature.

CPD for staff is addressed through internal and external training and courses. This was evident from the discussions held with staff.

The PR stated that he takes an active role together with Trust's HR department in the recruitment of staff and their suitability to work within the unit.

Areas for improvement

Staff to ensure that all laboratory procedures are witnessed.

Executive recommendations for Licence Committee

Witnessing of procedures in the laboratory is not documented. This is breach of the witnessing Directions D.2004/4.

Areas not covered on this inspection

PGS/PGD.

Evaluation

Some improvements required.

Report compiled by:

Name……..…Parvez Qureshi…….

Designation……Inspector……..

Date……12 February 2007……

Appendix A: Centre Staff interviewed

PR and 5 other members of the staff

Appendix B: Licence history for previous 3 years

2006

Licence Committee 30th October 2006
The Committee agreed to recognise Mr Menem Yossry as the new Person Responsible for the centre.

Licence Committee of 10th April 2006
The Committee agreed to issue the centre with a treatment and storage licence. This licence had no additional conditions attached and is to last for three years.

2005

Licence Committee of 28th April 2005
The Licence Committee agreed to the renewal of the centre's storage licence for a period of 12 months.

2004

Licence Committee of 11th November 2004
The Licence Committee agreed to the renewal of the centre's licence for six months with the donor insemination being suspended for the first three months of this period.
The Licence Committee agreed to recognise Dr Janine Elson as the Person Responsible.

Licence Committee of 18th August 2004
The Licence Committee agreed to the continuation of the centre's licence and made three recommendations.

Licence Committee 24th May 2004
The Licence Committee agreed to vary the centre's licence to recognise Mr Craig Steele as Person Responsible subject to an additional letter to confirm the application from the Nominal Licensee.

Licence Committee 5th April 2004
The Licence Committee agreed to vary the centre's licence to recognise Mr Ken Bremmer as Nominal Licensee.

Inspection 11th May 2004

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0096.

Name of PR……..…Mr Menem Yossry.

Date of Inspection……...18 January 2007.

Date of Response……8th March 2007.

Please state any actions you have taken or are planning to take following the inspection with time scales

Immediately following the inspection, systems were put in place to achieve full compliance with the inspection team's recommendations and to improve any aspects of the service if required. Changes were made with immediate effect.

I have read the inspection report and agree to meet the requirements of the report.

Signed…..A signed hardcopy received from PR.

Name…....M Yossry.

Date……..8th March 2007.

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

16 April 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Sunderland Fertility Centre (0096)
Interim Inspection

Members:
Walter Merricks, Lay Member – Chair
Ruth Fasht, Lay Member
Jennifer Hunt, Senior Infertility Counsellor, Hammersmith Hospital
Hossam Abdalla, Director of Lister Fertility Centre

In Attendance:
Trish Davies, Director of Regulation
Frances Clift, Legal Adviser
Claudia Lally, Committee Secretary

Observing:
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary

Conflicts of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (28 pages)
- no papers were tabled.

1. The papers for this item were presented by Parvez Qureshi, HFEA Inspector. Mr Qureshi reminded the Committee that this centre carries out a very small number of licensed treatments, amounting to about five donor insemination cycles per year. The centre has a good history of regulatory compliance and has recently acquired a new Person Responsible, who is settling in well. This recent change has brought the centre's risk score up to 11%.

2. Mr Qureshi informed the Committee that the inspection team had noted a number of improvements since the previous inspection but also identified a number of areas for further improvement. In particular, the team noted that laboratory procedures were not being double-witnessed in compliance with Directions D.2004/4. Furthermore, a number of recommendations were made by the team in relation to the requirement to update patient information and the

suggestion that patients are able to contact the counsellor directly rather than through the centre.

3. Mr Qureshi drew the Committee's attention to the response of the Person Responsible to these issues, appended to the report at annex C. This response confirmed that full compliance with the team's recommendations was achieved by the centre immediately after the inspection.

4. The breach of Directions D.2004/4 was noted by the Committee as was the Person Responsible's quick and comprehensive response to the issues raised at the inspection.

5. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Walter Merricks (Chair)